

ELECTROPROCESSING IN DRUG DELIVERY AND CELL ENCAPSULATION

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PRIOR RELATED APPLICATIONS

This application claims priority to U.S. provisional patent application serial number 60/241,008 filed October 18, 2000, U.S. provisional patent application serial number 60/270,118 filed February 22, 2001, U.S. non-provisional patent application serial number 09/714,255 filed November 17, 2000, and U.S. non-provisional patent application serial number 09/946,158 filed September 4, 2001.

FIELD OF THE INVENTION

The present invention relates to novel compositions comprising electroprocessed materials with substances, and methods of making and using these compositions in delivery of substances.

BACKGROUND OF THE INVENTION

Numerous methods exist for delivering substances to desired locations in vivo or in vitro. One such method uses devices or objects that contain a substance and will release the substance within a desired location. One desirable application for such methods is the administration of such objects to a location within the body of an organism, followed by the subsequent release of the desired substance into the body. In these examples, the implant often contains the substance and a carrier. After implantation, the substance is released by a variety of means including, for example, diffusion from an implant or dissolution or other degradation of a capsule coat.

Biocompatibility is a desirable attribute in compositions designed for substance delivery. With surgical and subdermal implants, for example, the substance to be delivered is often contained in a matrix comprised of synthetic polymers. Where natural products are used in making bandages, the products typically comprise wood products such as cellulose or other materials that are not readily absorbed by the body of the recipient. Accordingly, such bandages must eventually be removed. Implants compressed from natural materials that may be

absorbed by the body are one way to improve biocompatibility and is one area in which improvements are desired.

There is also a continuing need for greater versatility and flexibility in substance delivery technology. Additional techniques for controlling release kinetics and spatial patterns of release or delivery are examples of developments that can improve substance delivery. Implants in which there is refined control of structure at the microscopic or molecular level and overall implant shape are also desired. Such methods could allow, for example, further refinements in control of pore size or other attributes that affect diffusion in and out of a matrix, or more refined control of the distribution of a substance within a matrix. New methods that allow encapsulation of living cells within a matrix are especially desired. Such methods would allow implants to contain, for example, cells that produced desired substances, cells that promote tissue growth, or cells that serve both of these functions.

What is needed therefore are new compositions for use in drug delivery that provide additional and improved methods of controlling configuration of drug delivery systems. Compositions with improved biocompatibility compared to those currently used in substance delivery and/or that can contain living cells are also needed. What is further needed are new methods of substance delivery using such compositions. Finally, methods for making such compositions are also needed.

SUMMARY OF THE INVENTION

The present invention seeks to overcome the limitations in the prior art by providing compositions comprising an electroprocessed material and a substance. The substance may be the material itself, or another substance which may be delivered with the electroprocessed material to a desired site. Sometimes the compositions comprising an electroprocessed material and a substance are in the form of a matrix. The electroprocessed materials include any natural or non-natural materials or blends thereof. The substance is released from the composition or causes the release of molecules or compounds from the composition. Substance release can occur in vitro, in vivo, or both.

The present invention also includes a method for delivery of substances to a location using the present compositions comprising an electroprocessed material and a substance. The locations can be in vitro, in vivo, or both. The

invention also includes methods for making the compositions of the present invention.

The compositions of the present invention include an electroprocessed material and a substance. The material can include naturally occurring materials, 5 synthetically manufactured materials, or combinations thereof. Naturally occurring materials include natural organic or inorganic materials, genetically engineered materials and include synthetic alterations thereof. Synthetic materials include materials prepared through any method of artificial synthesis, processing, or manufacture. The invention includes materials that degrade and 10 can be absorbed by the body, or will persist in whole or in part and become portions of an extracellular tissue matrix. The compositions may be made using any electroprocessing technique, including but not limited to electrospinning, electroaerosol, electrospraying or electrosputtering techniques, or any combination thereof. Accordingly, electroprocessed droplets, particles, fibers, 15 fibrils, or combinations thereof are all included in the compositions of the present invention. In a preferred embodiment, the electroprocessed materials form a matrix, and in some cases are similar to an extracellular matrix. Matrices may also be formed from materials that can combine to form another material, such as precursor materials. For example, fibrinogen, when combined with thrombin, 20 will form fibrin.

Any material that may be electroprocessed may be used to form an electroprocessed material to be combined, either before, during or after electroprocessing, with a substance, to form the compositions of the present invention. The compositions of the present invention contain one or more 25 substances. The substance includes any type of substance desired, with examples including molecules, cells, objects, or combinations thereof. In some cases, the substance is the electroprocessed material itself. Molecules can be any size, complexity, or type, including both organic or inorganic molecules as well as any combination of molecules. Molecules include naturally occurring and synthetic 30 molecules. Examples of molecules include, but are not limited to therapeutics, cosmetics, nutraceuticals, vitamins, minerals, humectants, molecules produced by cells, including normal cells, abnormal cells, genetically engineered cells and cells modified through any other process. Both eukaryotic and prokaryotic cells are included in the category of substances. Substances also include, without 35 limitation, antigens, antimicrobials, antifungals, molecules that can cause a